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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,565	03/11/2004	Steven M. Griffiths	11201-735-999	4820
20583	7590	07/09/2008	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017		MACNEILL, ELIZABETH		
		ART UNIT		PAPER NUMBER
		3767		
		MAIL DATE		DELIVERY MODE
		07/09/2008		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/797,565	GRIFFITHS, STEVEN M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ELIZABETH R. MACNEILL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 May 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7,9-16 and 18-29 is/are pending in the application.  
 4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7,9-16,18-21,28 and 29 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

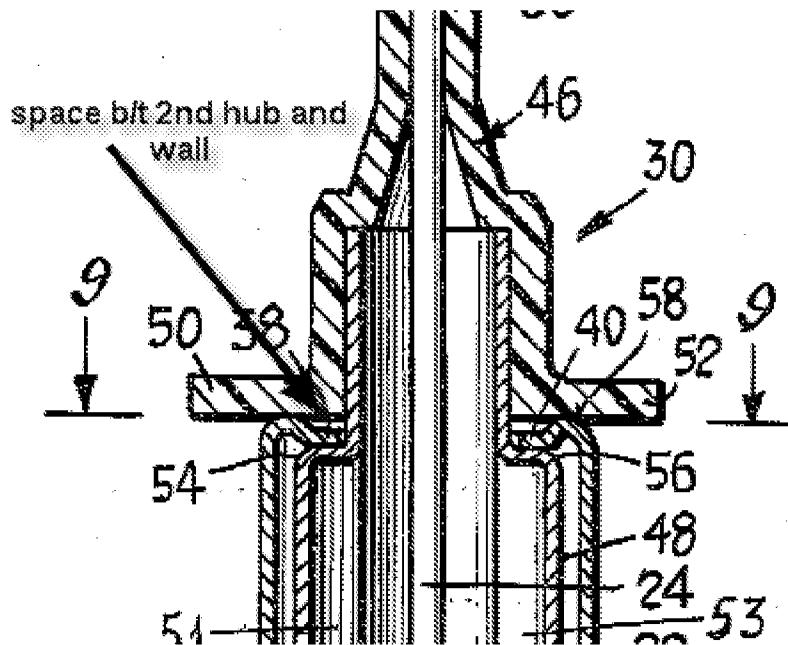
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruck (US 3,974,832).

3. Regarding claim 1, Kruck teaches (**see embodiment of Fig 1**) a needle and hub assembly for an injection device, comprising: a cap (26) having an engaging portion (28) adapted to engage an exterior surface of a cartridge (12), and a needle-supporting portion having a wall with a front surface (38,40) that includes an opening therein, the wall defining interior and exterior surfaces (Fig 1); a first hub portion (48) defining a needle-receiving channel (51,53) through the opening in the wall and having a section that extends along the interior surface of the wall (54,56); a needle (24) mounted in the needle-receiving channel and extending outwardly therefrom; and a second hub portion (46) engaged with the first hub portion (around 30) and receiving at least a portion of the needle (supporting portion at 55), the second hub portion having reinforcing structures (50, 52) which extend outwardly along the exterior surface of the wall; wherein the wall of the needle-supporting portion of the cap is reinforced on the interior surface by the first hub portion and on the exterior surface by the second hub portion. See Figure 1.

As to claims 1 and 16, Kruck does not teach that the 1<sup>st</sup> hub, 2<sup>nd</sup> hub, and wall are sandwiched together. Kruck seems to show a space between the 2<sup>nd</sup> hub and the wall (portion of Fig 1 labeled below):



Kruck teaches that "The fully locked position is defined by engagement of the flanges 50, 52 of the cup portion 46 with the upper surface 58 of the ferrule, and by engagement of the hub shoulders 54, 56 with the inclined shoulders 38, 40 of the ferrule." See Fig 3, which shows that on upper wall 58, there is an inclined groove extending partway around the wall (see also Fig 2). It is the examiner's position that the cross-section shown in Fig 1, which shows the gap, is taken at a low point in the inclined groove, and that at another point along the wall, the wall will be flush with the 2nd hub at 50/52. Furthermore, Kruck does not teach any reason for having a gap or why this gap is important to the function of his invention. It would have been obvious to one of ordinary skill in the art at the time the invention was made to flatten top 58 so

that a sandwich is formed from 1st hub to wall 2nd hub to further reinforce the wall portion.

As to claim 2, the first and second hubs are fused by press fit.

Regarding claims 3-6, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use metal and plastic to form the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

Regarding claim 7 (and 10), flanges 50 and 52 are considered radially-extending ribs.

Regarding claim 9, the needle-receiving channel provides a continuous flow pathway from the inside of the cap to the outside of the cap (via needle lumen).

Regarding claim 28 (and 29), the 1st hub (which defines the needle receiving channel) has two stops-shoulder 56 and its distal most end-which abut the wall and 2nd hub. The 2nd hub holds the needle and abuts the end of the first hub (approximately at 46, Fig 1 or 6). Therefore, the distal most end of the 1st hub has stop which limits the insertion depth of the needle within the first hub portion.

4. Claims 10-16, 18-21, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruck in view of Sarnoff et al (US 4,755,169).

Regarding claim 10, Kruck teaches a needle and hub assembly for an injection device, as described above. Kruck fails to teach that the assembly is used with an automatic injector with a stored energy source.

Sarnoff teaches an automatic injector with a hub assembly (526), plunger (558), cartridge (546) and a stored energy means (spring 564). See Figs 10-13

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the stored energy means of Sarnoff with the hub assembly of Kruck in order to provide a means for automatically injecting a medicament into a patient by applying less force to the plunger (i.e. allowing the stored energy means to provide force to the plunger).

Regarding claims 12-15, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use metal and plastic to form the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

Regarding claim 19, the cartridge has two medicament compartments (552, 540, Sarnoff).

Regarding claim 20, one of the medicament compartments is adapted to house a wet medicament component (552) and the other medicament compartment is adapted to house a dry medicament compartment (540, Sarnoff).

Regarding claim 21, the at least one opening in the cartridge is in the dry medicament compartment (Sarnoff Fig 10).

### ***Response to Arguments***

Applicant's arguments have been considered but are not persuasive. As to claims 1 and 16, the amendments are overcome by obviousness rejection stated above. The

"sandwiching" is obvious for two reasons: first, the examiner believes this may be already shown because of the slanted slots in the wall 58, and because one of ordinary skill in the art could easily modify device to remove the gap. As to claim 10, flanges 50 and 52 are reinforcing ribs. Further as to claim 10, applicant contends that medicament may leak out of the combination device because of the needle piercing the vial prior to use. However, this is true of the Sarnoff device as well (Fig 10).

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/  
Examiner, Art Unit 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761